



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Charles L. Sawyers et al.

Serial No.:

10/067,705

Filed:

February 4, 2002

Docket:

30435.53USD7

Title:

PURIFIED HUMAN PROSTATE CANCER CELLS

CERTIFICATE UNDER 37 CFR 1.8

I hereby certify that this paper or fee is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313 on September 26, 2003.

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

Sir:

We are transmitting herewith the attached:

Transmittal sheet, in duplicate, containing Certificate under 37 CFR 1.8.

Information Disclosure Statement (37 C.F.R. §1.97(b)(3))

Form 1449 (Information Disclosure Statement)

Exhibits 9 – 40

Return postcard

Please charge any additional fees or credit overpayment to Deposit Account No. 50-0306. A duplicate of this sheet is enclosed.

MANDEL & ADRIANO

55 S. Lake Avenue, Suite 710 Pasadena, California 91101 (626)395-7801

Name: Sarah B. Adriano

Reg. No.: 34,470 Initials: SBA

Customer No: 26,941



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Charles L. Sawyers, et al.

Examiner:

Not Yet Known

Serial No.:

10/067,705

Group Art Unit:

1632

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By: Richelle Ann Domingo

55 S. Lake Avenue, Suite 710 Pasadena, California September 26, 2003

INFORMATION DISCLOSURE STATEMENT (37 C.F.R. §1.97(b)(3))

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement should be considered because it is submitted before the mailing date of the first Office Action on the merits according to 37 C.F.R. §1.97(b)(3). In accordance with 37 C.F.R. §1.98(d), copies of Exhibits 9-40 as set forth in the Form 1449 are included herewith.

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. They are as follows:

Charles L. Sawyers, et al. Serial No. 10/067,705 Filed: February 4, 2002

- Aldrovandi, Grace M. et al., "The SCID-hu Mouse as a Model for HIV-1 Infection," *Nature*, June 24, 1993, 363:732-6. (Exhibit 9)
- Batson, Oscar V., "The Role of the Vertebral Veins in Metastatic Processes," Ann. Int. Med.,
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- Coman, Dale Rex and Robert P. DeLong, "The Role of the Vertebral Venous System in the
 Metastasis of Cancer to the Spinal Column," Cancer, 1951, 4:610-8. (Exhibit 13)
- Deguchi, T. et al., "Detection of Micrometastatic Prostate Cancer Cells in the Bone Marrow of Patients with Prostate Cancer," *British Journal of Cancer*, 1997, 75(5):634-8. (Exhibit 14)
- Ellis, William J. et al., "Characterization of a Novel Androgen-Sensitive, Prostate-Specific Antigen-Producing Prostatic Carcinoma Xenograft: LuCap 23," Clinical Cancer Research, June 1996, 2:1039-48. (Exhibit 15)
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 (Exhibit 21)
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- Kjønniksen, Inge et al., "Validity and Usefulness of Human Tumor Models Established by Intratibial Cell Inoculation in Nude Rats," Cancer Research, April 1, 1994, 54:1715-9.
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- Nishijima, Yukiko et al., "Clinical Significance of the Vertebral Vein in Prostate Cancer Metastasis," Adv. Exp. Med. Biol., 1992, 324:93-100. (Exhibit 30)
- Noel, A. et al., "Basement Membrane Components (Matrigel) Promote the Tumorgenicity of
 Human Breast Adenocarcinoma MCF7 Cells and Provide an In Vivo Model to Assess the
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 (Exhibit 31)
- Pang, Shen et al., "Prostate Tissue Specificity of the Prostate-Specific Antigen Promoter Isolated from a Patient with Prostate Cancer," Human Gene Therapy, November 1995,
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 (Exhibit 33)
- Seiden, Michael V. et al., "Detection of Circulating Tumor Cells in Men with Localized Prostate Cancer," *Journal of Clinical Oncology*, December 1994, 12(12):2634-9. (Exhibit 34)
- Sutherland, Richard W. et al., "Androgen Receptor Gene Mutations are Rarely Associated with Isolated Penile Hypospadias," *The Journal of Urology*, 1996, 156:828-31. (Exhibit 35)
- Thalmann, George N. et al., "Androgen-Independent Cancer Progression and Bone
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• Wang, Min and Mark E. Stearns, "Isolation and Characterization of PC-3 Human Prostatic

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• Wood, David P. Jr. et al, "Identification of Bone Marrow Micrometastases in Patients with

Prostate Cancer," Cancer, 1994, 74:2533-40. (Exhibit 38)

• Wu, His-Chin et al., "Derivation of Androgen-Independent Human LNCaP Prostatic Cancer

Cell Sublines: Role of Bone Stromal Cells," Int. J. Cancer, 1994, 57:406-12. (Exhibit 39)

• Zetter, Bruce R. et al., "The Cellular Basis for Prostate Cancer Metastasis," Adv. Exp. Med.

Biol., 1992, 324:39-43. (Exhibit 40)

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102

and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish

that the reference(s) are not "prior art." Moreover, Applicants do not represent that the

references have been thoroughly reviewed or that any relevance of any portion of a reference is

intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of

M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked

as being considered and initialed by the Examiner, to the undersigned with the next official

communication.

6

Charles L. Sawyers, et al. Serial No. 10/067,705 Filed: February 4, 2002 Page 7

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-0306.

Respectfully submitted,

Sarah B. Adriano

Sarah B Ad

Registration No. 34,470

Attorney for Applicants Mandel & Adriano

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Customer No. 26,941

Application Number Docket Number FORM 1449* 10/067,705 30435.53USD7 INFORMATION DISE Applicant SURE STATEMENT Charles L. Sawyers et al. IN AN APPLICATION **Group Art Unit** Filing Date 1632 February 4, 2002 (Use several sheets if necessary)

| | | U.S. P | ATENT DOCUMENTS | 3 | | | |
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| EXAMINER INITIAL | DOCUMENT NO. DATE | | NAME | NAME CLASS | | FILING DATE IF APPROPRIATE | |
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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) |
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DATE CONSIDERED **EXAMINER**

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

*Substitute Disclosure Statement Form (PTO-1449) Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

FORM 1449*

STATEMENT INFORMATION DISCLOS

Docket Number 30435.53USD7 **Application Number** 10/067,705

Applicant

Charles L. Sawyers et al.

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Group Art Unit

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(Use several sheets if necessary)

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| | OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) |
| | Hsu, Su-Ming et al., "A Comparative Study of the Peroxidase-Antiperoxidase Method and an Avidin-Biotin Complex Method for Studying Polypeptide Hormones with Radioimmunoassay Antibodies," American Society of Clinical Pathologists, 1981, 75:734-8. (Exhibit 21) |
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